

**AMENDMENTS TO THE DRAWINGS:**

The attached replacement sheet of drawings include the following changes to the drawing figures: FIG. 1 is amended to properly indicate the first cylinder 52, which is described on page 10, lines 14-26 of the originally filed application. Accordingly, Applicants submit a replacement sheet and an annotated sheet showing the drawings changes to FIG. 1.

Attachments: Replacement Sheet (including changes to FIG. 1)  
Annotated Sheet showing changes to FIG. 1

### **REMARKS**

Claims 1-5 were pending in this application, with claim 1 being independent. By this Amendment, Applicants have amended claims 1, 4, and 5 in order to more clearly define the present invention. In particular, Applicants have amended claims 1, 4, and 5 to provide proper antecedent basis for the recitations therein. In addition, Applicants have rewritten claims 4 and 5 in independent form. Applicants have also added new claims 6-14 to further define the invention and have cancelled claims 2 and 3 without prejudice or disclaimer.

In the Office Action dated August 25, 2005, the Examiner objected to claims 2-4 under 37 C.F.R. § 1.75(c) as allegedly being in improper dependent form for failing to further limit the subject matter of a previous claim. In addition, the Examiner rejected claims 2-5 under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. Without conceding the appropriateness of the rejections (and objections), Applicants submit that the amendments submitted herewith render the outstanding rejections and objections moot.

Applicants respectfully request reconsideration and allowance of the application for the following reasons.

#### **Claim Rejections - 35 U.S.C. § 102**

In the August 25, 2005 Office Action, the Examiner rejected claim 1 as allegedly being anticipated by U.S. Patent No. 6,004,297 to Steinfeldt-Jensen et al. ("the '297 patent"). Applicants respectfully traverse this rejection.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P.

§ 2131 (8<sup>th</sup> ed. 2001), p. 2100-70, quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Claim 1 recites, *inter alia*, a dose dial and drive mechanism characterised in that when said dose dial sleeve travels towards the second end of said housing the reset sleeve is carried with said dose dial sleeve towards the second end of said housing thereby resetting said dose display to a zero position.

In rejecting independent claim 1, the Examiner equates the claimed reset sleeve with the “dose scale drum,” disclosed in column 3, line 31, of the '297 patent (and later referred to as item 17). (See August 25, 2005 Office Action, Page 3.) In addition, the Examiner equates the claimed dose dial sleeve to the generically described “dose setting mechanism” of column 2, line 51. The '297 patent, however, fails to teach or suggest any structure where travel of such structure towards the second end of a housing results in a resetting of a dose display to a zero position as claimed. To the contrary, in every figure disclosed in the '297 patent, any movement or travel of the dose scale drum 17 towards the second end (i.e. towards the non-dispensing end) actually results in an increase in the displayed dose.

As set forth in column 6, lines 15-18 of the '297 patent, “[n]umbers indicating set doses are printed on the outer wall of the dose drum 17 and the number corresponding to a set dose is shown in a window 18 provided in the side wall of the housing 1.” Any movement of the dose scale drum 17 in a direction corresponding to the claimed second end (i.e. upwards) is part of the dose selection process. Therefore, such travel necessarily results in an increase, and not a resetting, of the displayed dose.

With regard to the embodiment of FIGS. 1-5 of the '297 patent, for example, column 6, line 67 - column 7, line 13 discloses the dose selection process and the corresponding upwards travel of item 17. Only upon downward travel relative to the housing (i.e. towards the home position of item 17) does the display through window 18 decrease. See, for example the '297 patent at column 7, lines 14-26. Even then, there is no assured resetting function transferring the dose drum 17 to the zero display. For example, in the event that less than all of a selected dose is injected, a subsequent dose selection process would begin with the dose drum 17 erroneously displaying a non-zero value.

With regard to the embodiment of FIGS. 6-10, column 7, line 65 - column 8, line 9 of the '297 patent also discloses that upwards movement of item 17 corresponds to an increase in dosage. In the embodiment of FIGS. 11-13, item 17 is graphically depicted (in FIG. 13), in an arrangement where the second end of item 17 corresponds to a display setting indicating no dosage (i.e. zero). Therefore, proximal movement of item 17 during the dose selection process necessarily results in an increase in dosage. See, for example, the '291 patent at column 9, lines 33-44.

Finally, the embodiment of FIGS. 15-17 of the '297 patent also discloses that upwards movement of the scale drum 80 (an element similar to item 17 of FIGS. 1-5) corresponds to an increase in dosage. See, for example, the '297 patent at column 11, lines 47-50.

In contrast to the '297 patent, the invention of claim 1 recites an arrangement where, through travel of a dose dial sleeve, a reset sleeve is carried towards the second end of the device which in turn automatically resets the dose display to zero. Such an

arrangement assures that the dose display is always properly calibrated prior to the dose level selection and prior to administering any dose. Accordingly, the '297 patent fails to teach or suggest the recitations of independent claim 1. For at least the reasons presented above, Applicants respectfully request that the rejection of independent claim 1 and its dependent claims 81-83, 86-92, and 94-99 be withdrawn.

#### **NEW CLAIMS 6-14**

By this Amendment, Applicants have added new claims 6-14. Exemplary support for claim 6 is found at least in the originally filed specification at page 9, lines 20-27. Exemplary support for claims 7-9, 11, 12, and 14 is found at least in the originally filed specification at page 9, line 29 - page 11, line 2; and page 11, lines 27-32. Exemplary support for claims 10 and 13 is found at least in the originally filed specification at page 12, lines 5-23. No new matter has been added.

Regarding new claims 6-14, none of the cited prior art, alone or in combination, teaches or suggests the invention as claimed. Applicants request examination and favorable consideration of the newly submitted claims.

#### **CONCLUSION**

In view of the foregoing remarks, this claimed invention is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicants therefore respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: December 16, 2005

By: 

David M. Ruddy  
Reg. No. 53,945

**Attachments:** Replacement Sheet including changes to FIG. 1  
Annotated Sheet highlighting changes to FIG. 1



ANNOTATED MARKED-UP DRAWING

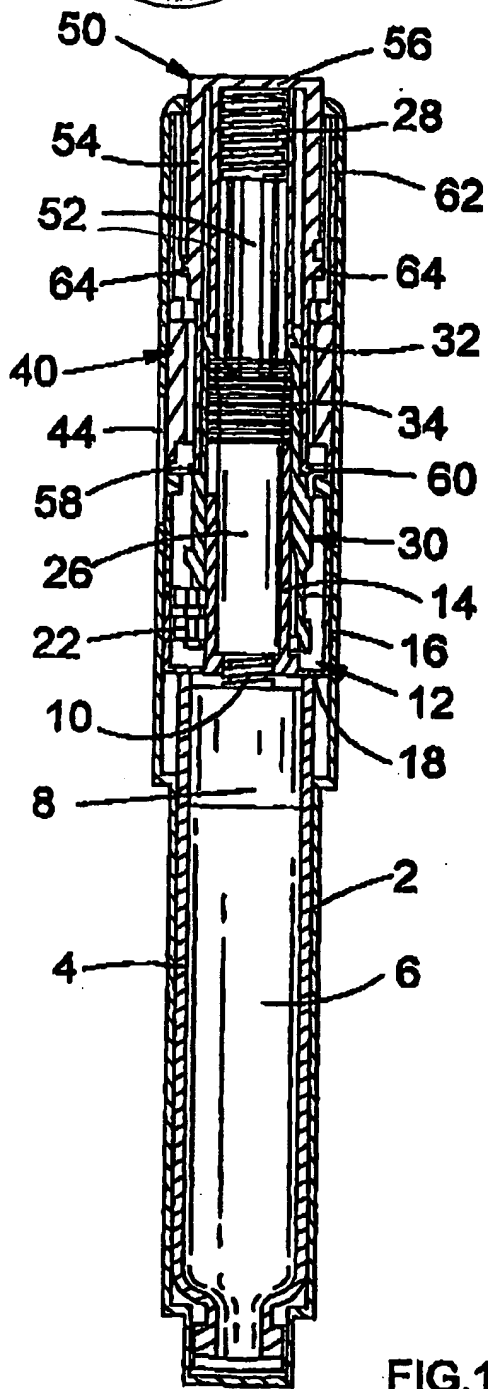


FIG.1

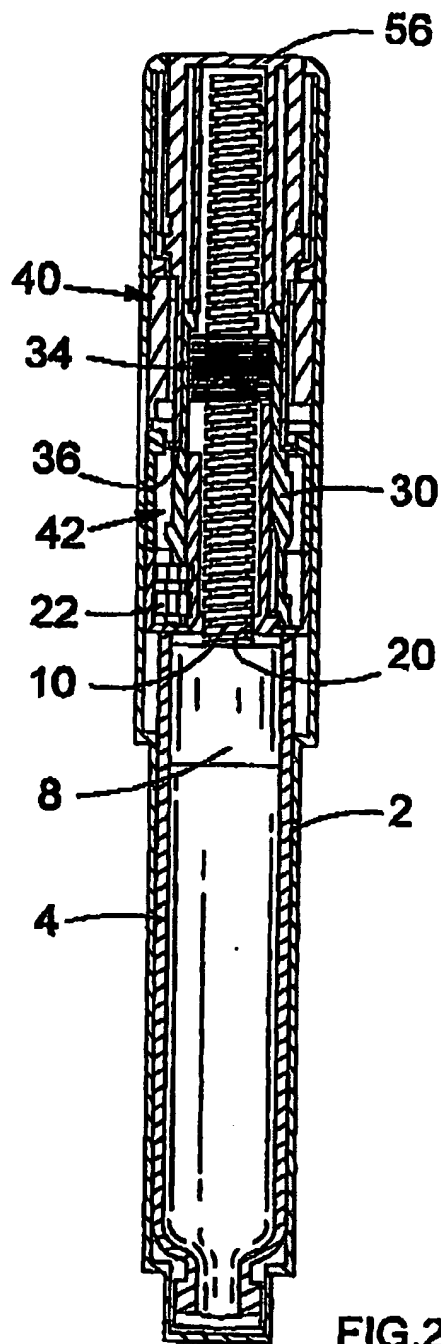


FIG.2